IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

MELANIE STACEL, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Case No. 08-CV-1143 Judge Joan B. Gottschall Magistrate Judge Jeffrey Cole

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S MOTION TO DISMISS

Defendant Teva Pharmaceuticals USA, Inc. ("Teva") respectfully submits this Reply Memorandum of Law in Further Support of Teva's Motion to Dismiss Plaintiff's Second Amended Complaint.

PRELIMINARY STATEMENT

In the instant Motion, Teva asked this Court to dismiss Plaintiff's Second Amended Complaint on two grounds. First, Plaintiff failed to plead her asserted causes of action based on common law fraud and the Illinois Consumer Fraud and Deceptive Business Practices Act ("Illinois Consumer Fraud Act") with the specificity required by Federal Rule of Civil Procedure 9(b). Second, without regard to the sufficiency of pleading, Plaintiff's state law claims are preempted by the Supremacy Clause of the United States Constitution and by federal law.

Plaintiff's Response to Teva's Motion to Dismiss ("Plaintiff's Response") contains little to contradict the arguments in Teva's moving papers, and even as to the points Plaintiff does address, her responses are insufficient to withstand the instant Motion. As to Rule 9(b),

Plaintiff's quotation of portions of the Second Amended Complaint serves only to highlight the insufficiency of the quoted allegations, and to further support Teva's argument. What Plaintiff patently does not do is justify the deficiencies of her fraud claims, which consist entirely of vague and unsupported allegations. As to federal preemption, Plaintiff fails to address the substance of Teva's argument altogether.

In short, Plaintiff's Response sets forth absolutely no basis for this Court to deny Teva's Motion to Dismiss Plaintiff's Second Amended Complaint.

ARGUMENT

1. Plaintiff's Fraud Claims Asserted in Counts II and III of Her Second Amended Complaint Do Not Satisfy the Heightened Pleading Requirements of Federal Rule of Civil Procedure 9(b)

As Teva has argued, Plaintiff has failed to allege with sufficient particularity her claims based on common law fraud and the Illinois Consumer Fraud Act. In her Response to Teva's Motion to Dismiss, Plaintiff offers little to dispute this argument. In fact, Plaintiff does nothing more than conclusively assert that her Second Amended Complaint meets the heightened Rule 9(b) standard, reproducing several paragraphs from the Second Amended Complaint that only serve to illustrate Teva's point that Plaintiff has not pled her fraud claims with sufficient particularity.

Plaintiff's Response opens with an acknowledgement that "[t]he heightened pleading requirements for fraud are well-established." (Pl.'s Response at 2.) Indeed, this Circuit strictly enforces this heightened requirement for pleading fraud claims:

> Rule 9(b)'s particularity requirement serves an important purpose. Accusations of fraud can seriously harm a business. . . . Rule 9(b) ensures that a plaintiff have some basis for his accusations of fraud before making those accusations and thus discourages people from including such accusations in complaints simply to gain leverage for settlement or for other ulterior purposes.

*Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 924 (7th Cir. 1992). Plaintiff further acknowledges that to satisfy the Rule 9(b) requirements, she "must 'state the time, place and content' of the alleged communications perpetrating the fraud." (Pl.'s Response at 2.)[1] However, having recognized these requirements, Plaintiff fails to demonstrate that she has satisfied them.

To start, Plaintiff has not identified the *content* of any alleged fraudulent statements made by Teva, even though she acknowledges that she must identify "the substance of the misleading statements and omissions that caused [her] injury" (Pl.'s Response at 2), and relies on case law that unequivocally holds that "pleadings must state the 'specific content of the false representations'" (Pl.'s Response at 2) (citing *Graue Mill Development Corp. v. Colonial Bank & Trust Co. of Chicago,* 927 F.2d 988, 992 (7th Cir. 1991) (dismissing complaint under Rule 12(b)(6) because plaintiff "has not alleged the *specific* content of any fraudulent statements or acts in its complaint") (emphasis in original); *see also D&G Enterprises v. Cont'l Ill. Nat. Bank & Trust Co. of Chicago*, 574 F. Supp. 263 (N.D. Ill. 1983)). Plaintiff contends that "the content of the fraudulent statements is spelled out in paragraphs 22 and 26 of the Second Amended Complaint." (Pl.'s Response at 2.) However, these paragraphs do not identify a single allegedly fraudulent statement made by Teva, or explain why Teva had a duty or reason to disclose any

[1] The Court should reject Plaintiff's attempt to minimize the Rule 9(b) requirements. Plaintiff cites a decision by this Court for the proposition that she is not required to "plead detailed evidentiary matters" (Pl.'s Response at 4) (citing *D&G Enterprises v. Cont'l Ill. Nat. Bank & Trust Co. of Chicago*, 574 F. Supp. 263, 267 (N.D. Ill. 1983)). However, the cited case unequivocally confirms Rule 9(b)'s heightened pleading standards, dismissing plaintiffs' complaint for "fail[ure] to state with specificity the time or circumstances under which the alleged violations or fraudulent acts took place." *Id.* at 267-68. The *D&G Enterprises* court points out that "[p]laintiffs fail to support their allegations with concrete examples, specific documents furnished to particular plaintiffs or instances in which one of the named plaintiffs was directly affected by [defendant's] activities." *Id.* at 268.

allegedly omitted statements or warnings. Rather, paragraphs 22 and 26 set forth a long list of allegations supported by no facts.

For example, in claiming that Teva failed to warn Plaintiff, her physicians, and the public of the dangers associated with minocycline (Second Am. Complaint ¶ 22), Plaintiff does not identify the specific unwarned dangers Teva should have warned about, does not offer proposed warning language Teva should have provided, and does not explain why FDA-approved warnings in Teva's minocycline label are inadequate to warn about dangers associated with the drug. Similarly, in alleging that Teva defrauded FDA by failing to follow FDA procedures concerning letters of approval, failing to seek changes in its minocycline label, and failing to report cases to the Adverse Event Reporting System (AERS) (Second Am. Complaint ¶ 22), Plaintiff does not point to any particular fraudulent letters of approval, does not propose label changes that Teva should have made, and does not identify specific cases that Teva withheld from the AERS.[2]

Further, in alleging that Teva made false statements in its promotional activities, in labels, and in information disseminated to various physicians including Plaintiff's physician (Second Am. Complaint ¶ 26), Plaintiff does not identify any specific fraudulent advertisements or promotions, does not provide Teva's allegedly fraudulent label, a public document, and does not specify what fraudulent information was disseminated to Plaintiff's physician. These are not peripheral allegations, but ones that go to the heart of Plaintiff's claims that she was fraudulently induced by Teva to take minocycline.

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[2] Teva notes, in any event, that "fraud on the FDA" claims are clearly preempted, *Buckman v. Plaintiff's Committee*, 531 U.S. 341, 350-51, 121 S. Ct. 1012, 1018-19 (2000), the Supreme Court having held unequivocally that such claims inevitably conflict with the FDA's responsibility to police fraud consistent with the Agency's judgment and objectives, and that no private right of action exists for such claims.

Plaintiff's Second Amended Complaint is equally vague with respect to *when* Teva allegedly made fraudulent representations or concealed material information. Plaintiff defines the time period as "when and before plaintiff consumed the drug" (Pl.'s Response at 2) – *i.e.* any time prior to July 2004 when Plaintiff began taking minocycline, or prior to March 30, 2005 when Plaintiff ceased taking minocycline (Second Am. Complaint ¶¶ 7, 12). Plaintiff has not provided even general dates of any of Teva's alleged misleading promotions or advertisements, dates of any of Teva's alleged fraudulent letters to FDA, dates when Teva allegedly disseminated misleading information to Plaintiff's physician, or dates of reported cases of drug-induced lupus that Teva allegedly failed to report to AERS.

Plaintiff's Second Amended Complaint provides no more detail with respect to *where* Teva made the allegedly fraudulent statements, stating only that "[t]he place of the false statements is the public domain." (Pl.'s Response at 2.) Again, Plaintiff does not identify specific promotions or advertisements containing alleged fraudulent statements, specific alleged fraudulent letters to FDA, specific pamphlets or other means by which Teva allegedly disseminated misleading information to Plaintiff's physician, or specific reports of drug-induced lupus that Teva failed to report to AERS.

Finally, even though Plaintiff herself states that "[m]ost importantly, complaints charging fraud must sufficiently allege the defendant's fraudulent intent" (Pl.'s Response at 5), neither Plaintiff's Second Amended Complaint nor her Response to Teva's Motion to Dismiss address Teva's intent in allegedly defrauding Plaintiff, the public, or FDA with respect to Teva's minocycline drug.

In sum, Plaintiff's Second Amended Complaint fails to provide a single specific example of misleading language in any of Teva's many alleged misrepresentations[3]. Plaintiff's definition of the time period and location of Teva's alleged misrepresentations could not be more vague or broad. Seventh Circuit courts have consistently held that fraud claims asserted with this lack of detail or supporting facts cannot meet Rule 9(b) requirements. *See Graue,* 927 F.2d 988; *D&G Enterprises*, 574 F. Supp. 263; *Sears v. Likens*, 912 F.2d 889, 893 (7th Cir. 1990) (dismissing complaint under Rule 12(b)(6) because the complaint "contains no specific information about the alleged fraudulent activities . . . [r]ather, the complaint proffers only conclusory allegations regarding such conduct."); *In re Bridgestone/Firestone Inc., Tires Prods. Liab. Litig.*, No. 01-5252, 2002 WL 31689264, at *8 (S.D. Ill. Nov. 20, 2002) (dismissing a products liability suit against Ford Motor Company because "[a]lthough the Complaint provides a general picture of Ford's allegedly wrongful conduct, it nowhere identifies specific communications by Ford that either constituted misrepresentations or, by virtue of their content, would have suggested a duty to disclose the allegedly omitted information. The Complaint provides no information as to the timing of such representations, the frequency, the medium by which they were transmitted, or any of the agents involved.")

Plaintiff recognizes that she has an obligation to "demonstrate due diligence in inquiring into the circumstances surrounding the fraud," (Pl.'s Response at 6), but improperly suggests that such due diligence can be demonstrated "through her attempts at furthering discovery in this case." *Id.* In fact, Plaintiff's due diligence obligation cannot be met by broad in-litigation discovery of Teva, conducted in the hope of unearthing something to support her litany of

[3] Nor, for that matter, does Plaintiff offer a single specific reason why Teva had a *duty* to disclose or warn about any additional information about its minocycline drug. *See In re Bridgestone/Firestone Inc., Tires Prods. Liab. Litig.*, No. 01-5252, 2002 WL 31689264, at *8 (S.D. Ill. Nov. 20, 2002).

unfounded fraud accusations. On the contrary, "[b]y requiring the plaintiff to allege the who, what, where, and when of the alleged fraud, [Rule 9(b)] requires the plaintiff to conduct a ***precomplaint investigation*** in sufficient depth to assure that the charge of fraud is responsible and supported, rather than defamatory and extortionate." *Ackerman v. N.W. Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999) (emphasis added); *see also In re Bridgestone*, 2002 WL 31689264, at *8. The bare and conclusory allegations in Plaintiff's Second Amended Complaint, repeated again in Plaintiff's Response to Teva's Motion to Dismiss, demonstrate either that Plaintiff performed no such precomplaint investigation, or that the facts to support her fraud allegations do not exist. Either way, Plaintiff's fraud claims must be dismissed.

2. Plaintiff's State Law Claims Fail Under the Doctrine of Federal Preemption

In its moving brief, Teva asked this Court to dismiss Plaintiff's claims on the grounds that these state law claims impermissibly conflict with federal law, and stand as an obstacle to implementation of Congressional objectives concerning the labeling of generic products. It is clear from Plaintiff's attempt in her Response to frame the issue as "a question of fact, not of law" (Pl.'s Response at 6), that she misconstrues Teva's argument. Whereupon, Plaintiff merely asserts that dismissal of her complaint under Rule 12(b)(6) is inappropriate, and declines the opportunity to address the substance of Teva's federal preemption argument. Because Plaintiff does not oppose Teva's moving papers in any meaningful way, little reply is needed from Teva, other than clarifying Plaintiff's misconception.

In fact, it is plain that, by its very definition, the issue of federal preemption is a purely legal one, involving the interaction of federal statutes and regulations with state law. Teva's Motion to Dismiss asserts that Plaintiff's claims are preempted as a matter of federal law, regardless of any facts Plaintiff might allege. As discussed in detail in Teva's moving brief, the

manufacture and sale of generic prescription drugs is a highly regulated industry under the jurisdiction of FDA. Because Plaintiff's state law claims concerning the warnings she alleges should have been provided are in conflict with various federal statutory provisions and regulations governing FDA's approval of Teva's minocycline product and its labeling, these state law claims are preempted as a matter of law. Nowhere in her Response does Plaintiff explain how any evidentiary support concerning Teva's compliance with FDA regulations would be relevant to Teva's purely legal argument that Plaintiff's claims are preempted by federal law and regulations. Put briefly, Plaintiff has all the information necessary to address Teva's Motion to Dismiss Plaintiff's state law claims on federal preemption grounds.[4]

For this reason, and contrary to Plaintiff's assertion, Teva's Motion to Dismiss Plaintiff's state law claims on federal preemption grounds was appropriately brought as a Rule 12(b)(6) motion. Just last week, in ruling on two Rule 12(b)(6) motions to dismiss on this exact issue of federal preemption of state law claims brought against several pharmaceutical companies, a federal district court in Minnesota unambiguously held that the federal preemption question "is purely legal in nature." *Mensing v. Wyeth, Inc., et al.*, No. 07-3919, at 2 n.1 (N.D. Minn. June 17, 2008) (Ex. A). Indeed, this conclusion is so common-sense that the *Mensing* court mentioned it in a footnote, devoting no time to discussion. The *Mensing* court proceeded to consider the issue of federal preemption in great detail, ultimately concluding that plaintiff's state law claims are preempted, and granting the motions to dismiss brought by defendant drug manufacturers Actavis and Pliva. The court's reasoning in granting the defendants' motions to dismiss is directly applicable to the instant case:

[4] As noted *supra* note 2, to the extent that Plaintiff's claims sound in fraud on the FDA, they are clearly preempted. *Buckman,* 531.U.S. at 350-51.

> Plaintiff's failure to warn claims against Actavis and Pliva rely on state law imposing a duty on the generic drug manufacturers to provide adequate warnings that Actavis and Pliva allegedly did not provide. . . . If Plaintiff's claims were not preempted, Actavis and Pliva would be forced to choose between complying with the federal law while being exposed to state tort liability, or unilaterally adding a heightened warning to their labels at the risk of exposing themselves to federal liability. This conflict would stand as an obstacle to the accomplishment and full purposes and objectives of the Hatch-Waxman Act, a key purpose of which is to increase the availability of low-cost generic drugs and to relax the generic approval and labeling process.
> . . .
> Plaintiff's failure to warn claims, insofar as they assert that Actavis and Pliva had an independent duty to seek to add safety information to MCP's label, again would directly conflict with the statutory scheme of the Hatch-Waxman Act and would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of the Act.
> . . .
> Finally, the Court turns to Plaintiff's argument that Actavis and Pliva were free to employ other means to warn health care professionals, such as submitting a "Dear Doctor" letter. The regulatory scheme, however, does not allow for ANDA manufacturers to send "Dear Doctor" letters. . . . The imposition of an independent duty on the part of the generic manufacture to send "Dear Doctor" letters would directly conflict with the statutory scheme of the Hatch-Waxman Act.

Mensing, No. 07-3919, at 16-17.

On June 13, 2008, another federal court applied the same reasoning to dismiss plaintiffs' state law claims against a generic drug manufacturer on the grounds of federal preemption. *Gaeta, et al. v. Perrigo Pharmaceutical Company, et al.*, No. 05-04115 (N.D. Cal. June 13, 2008) (Ex. B). The court held as follows:

> Plaintiffs' causes of action seek to hold Perrigo liable for, in part, failing to warn of risks on the labeling for its drug. Since including these warning [sic] would put the Perrigo's ANDA in jeopardy for failing to conform with the FDA's approved labeling for the listed drug, Plaintiffs' state law causes of action conflict with Perrigo's obligations under federal law.
> . . .

> The Court finds that Plaintiffs' causes of action are preempted to the extent that they allow for liability based on a lack of adequate warning on the company's OTC generic drug labeling for its 200mg ibuprofen product.

Id. at 9.

Teva respectfully asks the Court to consider the recent opinions by the *Mensing* and *Gaeta* courts, Teva's argument set forth above, and Teva's comprehensive argument set forth in its moving brief, and to conclude that Plaintiff's state law claims must be dismissed. Plaintiff's Response to Teva's Motion to Dismiss provides no opposition to Teva's arguments, and no reason for this Court to uphold her state law claims.

CONCLUSION

For all of the reasons set forth above and in Teva's moving papers, Plaintiff's Second Amended Complaint should be dismissed.

Date: June 26, 2008

TEVA PHARMACEUTICALS USA, INC.

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CERTIFICATE OF SERVICE

Ameri R. Giannotti, an attorney, certifies that on June 26, 2008 she electronically filed the foregoing REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S MOTION TO DISMISS using the ECF system which will automatically send e-mail documentation of such filing to the parties listed below.

s/ Ameri R. Giannotti
Ameri R. Giannotti

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Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Gladys Mensing,

Plaintiff,

v.

WYETH, INC. (d/b/a WYETH); SCHWARZ PHARMA, INC.; PLIVA, Inc.; TEVA PHARMACEUTICALS, USA, INC.; ALPHARMA, INC., d/b/a ALPHARMA PHARMACEUTICALS; UDL LABORATORIES, INC.; ACTAVIS ELIZABETH, LLC, and PUREPAC PHARMACEUTICAL CO.; and the following fictitious party defendants (whether singular or plural, individual or corporate): No. 1, that entity which originally obtained permission from the U.S. Food and Drug Administration to market the drug branded Reglan; No. 2, that entity which obtained permission from the FDA to market the Reglan, metoclopramide and/or metoclopramide HCI ingested by Gladys Mensing; No. 3, that entity which originally manufactured and sold any Reglan which was ultimately ingested by Gladys Mensing: No. 4, that entity which originally manufactured and sold any Reglan, metoclopramide and/or metoclopramide HCI which was ultimately ingested by Gladys Mensing: No. 5, that entity which marketed Reglan or generic metoclopramide and/or metoclopramide HCI, jointly and individually,

Defendants.

Civil No. 07-3919 (DWF/SRN)

MEMORANDUM OPINION AND ORDER

Daniel J. McGlynn, Esq., and Patty F. Trantham, Esq., McGlynn, Glisson & Koch, APLC; and Lucia J. W. McLaren, Esq., and Michael K. Johnson, Esq., Goldenberg & Johnson, PLLC, counsel for Plaintiffs.

Bridget M. Ahmann, Esq., and Erin M. Verneris, Esq., Faegre & Benson LLP; and Jeffrey R. Pilkington, Esq., and Tom Wagner, Esq., Davis, Graham & Stubbs, LLP, counsel for Defendant Wyeth, Inc.

Andrew J. Calica, Esq., and Henninger S. Bullock, Esq., Mayer Brown, LLP; and Erin M. Verneris, Esq., and Bridget M. Ahmann, Esq., Faegre & Benson LLP, counsel for Defendant Schwartz Pharma, Inc.

Joseph P. Thomas, Esq., Matthew V. Brammer, Esq., Rex A. Littrell, Esq., and Tiffany Reece Clark, Esq., Ulmer & Berne LLP; and Jan R. McLean, Esq., Tracy J. Van Steenburgh, Esq., and Dana M. Lenahan, Esq., Halleland Lewis Nilan & Johnson PA, counsel for Defendants PLIVA, Inc.

David L. Hashmall, Esq., Fellhaber Larson Fenlon & Vogt, PA, counsel for Defendants Teva Pharmaceuticals USA, Inc. and UDL Laboratories, Inc.

Bradley J. Linderman, Esq., and Michael D. Hutchens, Esq., Meagher & Geer, PLLP; and Richard A. Dean, Esq., Tucker Ellis & West, counsel for Defendants Alpharma Inc., Actavis Elizabeth, LLC, and Purepac Pharmaceutical Co.

INTRODUCTION

This matter is before the Court on a Motion to Dismiss brought by Actavis Elizabeth, LLC ("Actavis"); a Motion to Dismiss or for Summary Judgment brought by Pliva, Inc. ("Pliva"); and a Motion for Relief Under Fed. R. Civ. P. 56(f) brought by Plaintiff Gladys Mensing. For the reasons stated below, the Court grants Actavis's and Pliva's motions and denies Plaintiff's motion.[1]

BACKGROUND

In her Amended Complaint, Plaintiff alleges that on or about March 23, 2001, her physician prescribed the drug Reglan to her to treat diabetic gastroparesis. (Am. Compl.

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[1] The question presented by both Actavis's and Pliva's motions to dismiss is purely legal in nature. Accordingly, further factual discovery is unnecessary and Plaintiff's motion under Fed. R. Civ. P. 56(f) is denied.

¶ 27). The active ingredient in Reglan is metoclopramide ("MCP"). MCO, which is available in brand (Reglan) or generic form, is used to treat certain gastrointestinal disorders. Plaintiff alleges that she ingested Reglan/MCP from March 23, 2001, until March 2005, and that her long-term ingestion of Reglan/MCP caused her to develop tardive dyskinesia, a neurological movement disorder. (*Id.* ¶¶ 27, 32, 34, 37, 38.)

Both Actavis and Pliva manufacture MCP, a generic version bioequivalent of Reglan.[2] Reglan, the reference listed drug for MCP, was approved by the FDA in 1980. In March 1985, the FDA required that Reglan's label be updated to include a warning regarding the risk of developing tardive dyskinesia. Actavis and Pliva revised their insert labeling to comport to approved changes to the Reglan label. There is no dispute that the labels for both Actavis's and Pliva's MCP were at all relevant times the same as Wyeth's Reglan label.

Plaintiff asserts state-law tort claims against both Wyeth and the manufacturers of generic MCP. Although Plaintiff has asserted a variety of claims against Actavis and Pliva, at the core of all of Plaintiff's claims is the basic assertion that Actavis and Pliva failed to adequately warn about the association between long-term ingestion of MCP and movement disorders. For example, Plaintiff alleges that Actavis and Pliva ignored scientific and medical literature establishing a higher risk of developing tardive dyskinesia, failed to request a labeling revision to the FDA, and failed to report safety information directly to the medical community.

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[2] Defendant Wyeth, Inc., is the name brand manufacturer of Reglan.

Actavis and Pliva move separately to dismiss Plaintiff's claims against them, arguing that Plaintiff's claims are preempted by federal law.

DISCUSSION

I. Motions to Dismiss

A. Standard of Review

In deciding a motion to dismiss, a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged. *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id.* at 1964–65. This standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Id.* at 1965. The Court

evaluates a motion brought under Rule 12(c) under the same standard as a motion brought under Rule 12(b)(6). Fed. R. Civ. P. 12(c) and (h)(2).

B. Federal Preemption

A state law that conflicts with a federal law is preempted under the Supremacy Clause of the Constitution, U.S. Const. art. VI, cl. 2. *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-13 (1985). Congressional intent to preempt state law can either be expressed in statutory language or implied in the structure and purpose of federal law. *Id.* Implied preemption has two types—field and conflict preemption. Field preemption is inferred where Congress legislates so pervasively in a particular field that no room remains for supplementary state legislation. *Id.* Even if Congress has not completely displaced state regulation, preemption may occur when state law actually conflicts with federal law. *Id.* Conflict preemption arises when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Id.* (citing *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) and *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). State laws can be pre-empted by both federal statutes and federal regulations. *Id.* at 713.

Both Actavis and Pliva assert that Plaintiff's claims are conflict preempted. First, they argue that as generic drug manufacturers, they cannot comply with both federal law that requires their generic drug labels to be the "same as" the Reglan® label and with a state-imposed duty to heighten warning labels. In particular, Actavis and Pliva contend that it would be impossible for it to comply with both the Abbreviated New Drug

Application ("ANDA") provisions of the Food, Drug & Cosmetic Act ("FDCA") and the labeling requirements Plaintiff seeks to impose pursuant to state law. In addition, both Actavis and Pliva maintain that Plaintiff's claims are conflict preempted because the state laws pose an obstacle to Congressional objectives in enacting federal law applicable to generic drug manufacturers and vesting exclusive authority to regulate prescription drug labeling with the Food and Drug Administration ("FDA").

In support of their preemption arguments, both Actavis and Pliva point to the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or the "Act") (codified at 21 U.S.A. § 355(j)). The Hatch-Waxman Act codified the ANDA procedures being used by the FDA. Actavis and Pliva assert that under the ANDA procedures, a generic manufacturer is required to put exactly the same language on its warning labels as the listed drug.[3]

1. Regulatory Framework

To determine whether or not Plaintiff's claims are preempted, the Court must first understand the relevant regulatory framework. The FDA is the federal agency charged by Congress in the FDCA with regulating the manufacture, sale, and labeling of new prescription drug products that are marketed for human consumption and, in particular, to ensure the safety and efficacy of new drugs. 21 U.S.C. § 393. In this capacity, the FDA regulates the introduction of all new drugs. 21 U.S.C. § 355(b). Under 21 U.S.C. § 355(a), "[n]o person shall introduce or deliver for introduction into interstate commerce

[3] Despite the fact that the bases for Actavis's and Pliva's preemption arguments vary to some degree, the Court analyzes their motions to dismiss together.

any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." Section 355(b) applies to "pioneer" or "innovator" drugs. A manufacturer seeking approval to market a pioneer drug must submit a New Drug Application ("NDA"). 21 U.S.C. § 355(b). As part of the NDA, the manufacturer must submit, among other things, "full reports of investigations" on the drug's safety and effectiveness and "specimens of the labeling proposed to be used" for the new drug. 21 U.S.C. § 355(b)(1)(A)-(F). The FDA may refuse an application if it finds that the investigations "do not include adequate tests . . . to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(1).

In 1984, Congress amended the FDCA by passing the Hatch-Waxman Act. The legislative history of the Hatch-Waxman Act reveals that the primary purpose of amending the FDCA to implement the ANDA procedure was to increase the availability of low cost generic drugs by establishing a generic drug approval procedure. (*See* Aff. of Tiffany Reece Clark ("Clark Aff.") ¶¶ 2 & 3, Exs. A & B.) The FDCA, as amended, provides for an ANDA procedure that allows for the expedited FDA approval of a generic version of a drug previously approved under the FDA (a "listed drug").[4] *See* 21 U.S.C. § 355(j); *see also Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241 (Fed.

[4] A "listed drug" refers to a drug previously approved that serves as the basis for a generic drug. 21 C.F.R. § 314.3.

Cir. 2000) (explaining the ANDA process).[5] 21 U.S.C. § 355(j) applies to generic drugs, or drugs that are based on another previously FDA approved or "listed" drug. When a drug for which approval is sought is the "same as a listed drug," then an applicant may submit an abbreviated application complying with the ANDA provisions of 21 C.F.R. § 314.94. 21 U.S.C. § 355(j)(1); 21 C.F.R. § 314.92(a). The manufacturer of a generic drug must show that the generic drug has the same active ingredients and is the "bioequivalent" of the listed drug. 21 U.S.C. § 355(j)(2)(A)(ii) and (iv). In addition, an applicant filing an ANDA must submit:

> information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug . . . except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers.

21 U.S.C. § 355(j)(2)(A)(v) (emphasis added). To this effect, an ANDA applicant must submit a side-by-side comparison of the applicant's proposed labeling. 21 C.F.R. § 314.94(a)(8)(iv). The labeling for the proposed drug "must be the same as the labeling approved for the reference listed drug," with the exception of certain allowable changes. *Id.* These allowable changes may include:

> . . . differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.

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[5] Prior to the Hatch-Waxman Act, the FDA created an ANDA procedure for the approval of "duplicate" drug products. Those procedures were codified by the Hatch-Waxman Act. *See* 57 Fed. Reg. at 17951 (Apr. 28, 1992) (explaining that the Act adopted, with few modifications, the FDA's ANDA procedure for pre-1962 drugs).

Id.

The FDA will not approve an ANDA if information submitted by the applicant is "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug." 21 C.F.R. § 314.127(a)(7). Moreover, the FDA may withdraw approval of a generic drug if the labeling for the generic product varies from that of the listed drug. 21 C.F.R. § 314.150(b)(10).

2. Plaintiff's Claims

With this framework in mind, the Court must determine whether Plaintiff's claims against Actavis and Pliva conflict with the FDCA or the FDA regulations, so as to be preempted by the federal law. As a threshold matter, Plaintiff argues that there is a strong presumption against preemption. The Supreme Court has stated:

> In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (quotations omitted). Although commonly acknowledged, the presumption against preemption is not always appropriate. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 347-48 (2001). In the context of conflict preemption, which analyzes preemption in the absence of explicit Congressional intent, "the lack of a Congressional directive expressly approving or rejecting preemption in the context of drug labeling regulations is not determinative." *See Colacicco v. Apotex Inc.*, 521 F.3d 253, 265 & n.11 (3d Cir. 2008). Thus, the Court

must analyze the propriety of preemption where Congress has not explicitly expressed its intent.

Plaintiff alleges that Actavis and Pliva's MCP labels failed to adequately warn of the risk or prevalence of tardive dyskinesia. In particular, Plaintiff claims that the risk ratio of developing tardive dyskinesia was significantly higher than the ratio listed on the Reglan and MCP labels.[6] Actavis and Pliva argue that these failure to warn claims are preempted because they, as generic manufacturers, could not unilaterally alter their labels to include a warning that varied from that of the listed drug, Reglan. In addition, Actavis and Pliva argue that Plaintiff's failure to warn claims are preempted because they stand as an obstacle to the accomplishment of the full purposes and objectives of the FDCA, the Hatch-Waxman Act, and the corresponding regulatory scheme.

Plaintiff asserts that her state law claims do not present a conflict because compliance with both state and federal regulations is possible and that Actavis and Pliva could have provided stronger warnings about the risks posed by prolonged exposure to MCP without conflicting with FDA regulations. In particular, Plaintiff argues that Actavis and Pliva could have altered their labeling to strengthen warnings without prior approval of the FDA; sought FDA approval for such a change; or provided health care professionals with stronger warnings by other means, such as a "Dear Doctor" letter. The Court addresses each argument in turn.

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[6] This allegation is at the heart of all of Plaintiff's claims against Actavis and Pliva. Thus, all of Plaintiff's claims are essentially "failure to warn" claims and are encompassed by the Court's preemption analysis.

The Court first turns to Plaintiff's argument that Actavis and Pliva can, and are required to, strengthen their product warnings without prior FDA approval. After reviewing the statutory provisions of the Act, the legislative history of the Act, the Act's governing regulations, and comments made by the FDA[7], the Court concludes that a generic drug manufacturer may not unilaterally strengthen a label without prior approval of the FDA.

Under the statutory provisions of the Act, there is no dispute that Actavis's and Pliva's MCP labels were required to be "the same as the labeling approved" for Reglan when the initial ANDA applications were submitted. 21 U.S.C. § 355(j)(2)(A)(v). Plaintiff argues, however, that 21 U.S.C. § 355 (j)(2)(A)(v) does *not* apply to post-approval labeling. Instead, Plaintiff argues that the FDA regulations require both name brand and generic manufacturers to strengthen warning labels post-approval. The Court disagrees.

The FDA's own comments in implementing the Hatch-Waxman Act support the conclusion that a generic manufacturer is not free to unilaterally alter the labeling from that of the name brand drug. In particular, in a proposed rule implementing the Act, the FDA described various types of labeling differences that the FDA might consider

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[7] When Congress has not unambiguously expressed its intent as to a particular question of statutory interpretation, the Court will defer to the agency's answer on the issue if it is based on a permissible construction of the statute. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). Here, the FDA's position on the ability of a generic manufacturer to unilaterally alter its label is based on a permissible construction of the relevant federal statutes and promulgating regulations. Accordingly, that position is entitled to deference.

acceptable under the statute's permitted exceptions. *See* 54 Fed. Reg. 28872 at 28884 (July 10, 1989). Notably, the FDA emphasized limited exceptions to the requirement that a generic drug label be the "same as" that of the listed drug. *Id.* The FDA stated that "[t]he agency will not accept ANDA's for products with significant changes in labeling (such as new warnings or precautions) intended to address newly introduced safety or effectiveness problems not presented by the listed drug." *Id.*

In addition, under the statutory scheme, the FDA may withdraw an ANDA if the ANDA drug labeling "is no longer consistent with that for the listed drug." 21 C.F.R. § 314.150(b)(10). In this regard, the FDA has explained:

> Because an ANDA must have labeling that is the same as the reference listed drug . . . , FDA believes that a generic drug product approved on the basis of studies conducted on the listed drug and whose labeling is inconsistent with the listed drug's labeling might not be considered safe and effective for use under the conditions prescribed, suggested, or recommended in the listed drug's labeling. FDA, therefore, has revised § 314.150 to permit the agency to withdraw approval of an ANDA if the applicant fails to maintain labeling in compliance with the requirements of the act.

57 Fed. Reg. 17950 at 17961 (Apr. 28, 1992) (emphasis added).

Several FDA responses to comments submitted in connection with proposed ANDA regulations underscore the notion that the ANDA drug's label must remain the same as that of the listed drug. For example, in response to a comment proposing that ANDA labeling provisions be "revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions and other safety-related information," the FDA stated:

> FDA disagrees with the comment[]. Except for labeling differences due to exclusivity of a patent and differences under section 505(j)(2)(v) of the act, the ANDA's product labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval. Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart. (See 54 FR 28872 at 28884.) If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

Id. at 17961 (emphasis added). In addition, in response to a comment recommending that the "FDA accept ANDAs with warnings or precautions in addition to those on the reference listed drug's label, provided that such information was not indicative of diminished safety or effectiveness of the generic product," the FDA stated:

> As for accepting ANDA's with additional warnings or precautions, section 505(j)(2)(A)(v) and (j)(3)(G) of the act requires that the applicant's proposed labeling be the same as that of the reference listed drug unless: (1) The labeling differences are due to an approved petition under section 505(j)(2)(C) of the act (otherwise referred to as a "suitability petition"); or (2) the drug product and the reference listed drug are produced or distributed by different manufacturers. Thus, the exceptions in section 505(j)(2)(A)(v) of the act are limited. In addition, under the patent and exclusivity provisions of the act, the ANDA labeling may be required to carry fewer indications than the reference listed product's labeling or to have other labeling differences. In the preamble to the proposed rule, the agency described various types of labeling differences that might fall within the permitted exceptions.

Id. at 17953 (citations omitted).

Further, in industry guidance documents, the FDA reiterates the ANDA labeling requirements. For example, in its Guidance for Industry regarding Changes to an Approved NDA or ANDA, the FDA states:

> A drug product labeling change includes changes in the package insert, package labeling, or container label. An applicant should promptly revise all promotional labeling and drug advertising to make it consistent with any labeling change implemented in accordance with the regulations. All labeling changes for ANDA products must be consistent with section 505(j) of the Act [codified at 21 U.S.C. § 355(j)].

(Clark Aff. ¶ 15, Ex. N. at 20 (emphasis added).) Again, section 505(j) (codified at 21 U.S.C. § 355(j)) requires that the labeling be the "same as" the listed drug.

That a generic drug manufacturer cannot unilaterally change the label is also supported by the positions of the FDA provided in recent *amicus briefs*. For example, in an *amicus brief* filed in *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), the FDA asserted the following:

> For a generic drug manufacturer, there is no statutory or regulatory provision permitting a labeling change to be made without prior FDA approval. To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug. If a generic drug manufacturer believes that new safety information should be added to the label for its drug, it is directed to contact FDA with "adequate supporting information." 57 Fed. Reg. at 17,961. The agency will consider this information and determine whether the labeling for both the generic drug and the innovator drug should be revised. *Id.*

(Clark Aff. ¶ 19, Ex. Q at 7-8.)[8]

[8] The Third Circuit recognized that the "FDA states that generic drug manufacturers may not add new warnings to the approved labeling for the listed drug." *Colacicco*, 521 F.3d at 260 n.5.

Plaintiff relies primarily on 21 C.F.R. § 314.70(c), the "Changes Being Effected" ("CBE") regulation, for the proposition that generic drug manufacturers can change their product labels without waiting for FDA approval.[9] Section 314.70(c) allows NDA manufacturers, under certain limited circumstances, to strengthen warnings prior to FDA approval. The FDA has explained, however, that the CBE provision does *not* permit ANDA manufacturers to make unilateral changes. In particular, the FDA explained:

> The plaintiff asserts that 21 C.F.R. § 314.70(c) empowers a generic drug manufacturer to add a new warning to the label for its drug without prior FDA approval. That regulatory provision, however—like the other provisions of Title 21, Part 314, Subpart B of the Code of Federal Regulations—applies to applications involving drug products for which a full application has been submitted, *i.e.*, innovator drug products. Drug manufacturers that submit abbreviated applications to market generic drugs are subject to the requirements set forth in Title 21, Part 314, Subpart C. Although Subpart C contains a provision requiring applicants to "comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application," 21 C.F.R. § 317.97, that provision does not modify the requirement that the drug label for a generic drug must be the same as the label for the approved innovator drug (with limited exceptions not relevant here). Any ambiguity in the regulatory text has been clarified by FDA, which explained at the time of promulgation that the regulations do not authorize drug manufacturers to add new warnings to the approved labeling for the innovator drug. *See* 57 Fed. Reg. at 17,961, 17,953, 17,955.

(Clark Aff. ¶ 18, Ex. Q at 8 n.4 (emphasis added).) In addition, in a rule proposed on January 2008, the FDA confirmed that § 314.70 does not permit unilateral label changes

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[9] With the Court's permission, Pliva submitted a copy of an *amicus brief* filed by the United States in a case currently before the United States Supreme Court. Pliva contends that portions of the argument therein would be helpful to the Court, particularly with respect to the interpretation of § 314.70(c). Plaintiff has moved to strike Pliva's submission. The Court denies Plaintiff's motion. While the Court reviewed Pliva's submission and the attached *amicus brief*, this review did not alter the Court's analysis or the outcome of the dispositive motions before the Court.

by ANDA manufacturers. *See* 73 Fed. Reg. 2848 at 2848-49 (Jan. 16, 2008). In particular, the FDA stated: "FDA is proposing to amend its regulations regarding changes to an approved NDA, BLA, or PMA to codify the agency's longstanding view on when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency's review." *Id.* at 2849. In the Supplementary Information section of the proposed rule, the FDA explains: "CBE changes are not available for generic drugs approved under an [ANDA] application under 21 U.S.C. 355(j). To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug." *Id.* at 2849 n.1 (citations omitted).

The Court concludes that under the federal statutory scheme, the labeling for generic drugs must always remain the "same as" that of the name brand drug and that a generic drug manufacturer cannot unilaterally change its label without prior FDA approval. Here, it is undisputed that at all relevant times, Actavis's and Pliva's MCP drug labels were the same as that of the listed drug Reglan. Plaintiff's failure to warn claims against Actavis and Pliva rely on state law imposing a duty on the generic drug manufacturers to provide adequate warnings that Actavis and Pliva allegedly did not provide. Any such duty to unilaterally heighten their warning labels, however, would directly conflict with the federal law requiring that their labels be the "same as" those of the listed drug, Reglan. Indeed, under these circumstances, it would be impossible for Actavis and Pliva to abide by both state and federal laws. If Plaintiff's claims were not preempted, Actavis and Pliva would be forced to choose between complying with the federal law while being exposed to state tort liability, or unilaterally adding a heightened

warning to their labels at the risk of exposing themselves to federal liability. This conflict would stand as an obstacle to the accomplishment and full purposes and objectives of the Hatch-Waxman Act, a key purpose of which is to increase the availability of low-cost generic drugs and to relax the generic approval and labeling process.

The Court turns next to Plaintiff's argument that Actavis and Pliva could have sought to strengthen their warnings through the prior approval supplemental process under 21 C.F.R. § 314.70. Based on the statutory scheme discussed above, the Court discerns no legal duty requiring a generic drug manufacturer to propose revised labeling. While the manufacturer of a generic drug may seek to add safety information to a drug label, in order to do so, it must first provide certain information to the FDA; the FDA then in turn determines whether the labeling for both the generic and listed drug should be revised. *See* 57 Fed. Reg. 17950 at 17961 cmt. 40. The outcome of any such request to make a revision is uncertain and would require speculation as to what the FDA might have done. In light of the statutory scheme discussed in detail above, the Court determines that Plaintiff's failure to warn claims, insofar as they assert that Actavis and Pliva had an independent duty to seek to add safety information to MCP's label, again would directly conflict with the statutory scheme of the Hatch-Waxman Act and would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of the Act.

Finally, the Court turns to Plaintiff's argument that Actavis and Pliva were free to employ other means to warn health care professionals, such as submitting a "Dear Doctor" letter. The regulatory scheme, however, does not allow for ANDA manufacturers to send "Dear Doctor" letters. Instead, for drugs approved through the ANDA procedures, "the Secretary shall undertake any communication plan to health care providers required under [the risk evaluation and mitigation strategies][10] for the applicable drug." 21 U.S.C. § 355-1(i)(2)(A). The imposition of an independent duty on the part of the generic manufacture to send "Dear Doctor" letters would directly conflict with the statutory scheme of the Hatch-Waxman Act. In addition, this Court's speculation over what the FDA might have done if Actavis or Pliva had requested such a letter would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of the Act.

CONCLUSION

Accordingly, **IT IS HEREBY ORDERED** that:

1. Actavis's Motion to Dismiss (Doc. No. 39) is **GRANTED**.
2. Pliva's Motion to Dismiss (Doc. No. 64) is **GRANTED**.
3. Plaintiff's Rule 56(f) Motion is **DENIED**.
4. Plaintiff's Motion to Strike (Doc. No. 85) is **DENIED**.
5. This action is dismissed as to Defendants Actavis and Pliva.

Dated: June 17, 2008

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court

[10] This includes sending letters to health care providers. 21 U.S.C. § 355-1(e)(3)(A).

Exhibit B

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

Margarita Gaeta, as guardian ad litem for A.G., a minor child, et al.,

Plaintiffs,

v.

Perrigo Pharmaceuticals Company, et al.,

Defendants.

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NO. C 05-04115 JW

ORDER GRANTING DEFENDANT PERRIGO'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Margarita Gaeta and Augustine Gaeta (collectively, "Plaintiffs"), bring this diversity action on behalf of their son, A.G., against Perrigo Pharmaceuticals Company ("Perrigo"), PAR Pharmaceutical Inc. ("PAR"), and BASF Corporation ("BASF") (collectively, "Defendants"), alleging, *inter alia*, strict products liability, breach of warranty, and negligence. Plaintiffs allege A.G. suffered liver failure as a result of his consumption of ibuprofen manufactured and distributed by Defendants.

Presently before the Court is Defendant Perrigo's Motion for Summary Judgment. (hereafter, "Motion," Docket Item No. 156.) The Court conducted a hearing on April 14, 2008. Based on the papers submitted to date and oral arguments of counsel, the Court GRANTS Defendant Perrigo's Motion for Summary Judgment.

II. BACKGROUND

A. Factual History

On June 3, 2004, A.G. had two benign moles removed in a surgical procedure. (Second Amended Complaint ¶ 21, hereafter, "SAC," Docket Item No. 29.) During the procedure, A.G.'s anaesthesiologist administered Halothane, an anesthetic known to cause liver failure in certain circumstances. NEIL KAPLOWITZ & LAURIE D. DELEVE, DRUG-INDUCED LIVER DISEASE 406-07 (Inferma Health Care 2003). After the surgery, A.G. was discharged with instruction to take 400mg of ibuprofen once every six hours as needed for pain. (Declaration of Kelly J. Savage, hereafter, "Savage Decl." Ex. B at 116:15-117:7, Docket Item No. 158.)

Plaintiffs purchased a bottle of Perrigo's generic over-the-counter ("OTC") ibuprofen at 200mg per tablet. (SAC ¶ 22.) From June 3 to June 6, 2004, A.G. took 400mg of the ibuprofen every six to eight hours.[1] On June 11, 2004, A.G. developed a fever, and he was seen by his pediatrician. A.G.'s pediatrician prescribed prescription-strength ibuprofen (400mg) to him. (Savage Decl., Ex. D 109:20-111:20.) However, A.G's condition continued to worsen: on June 13, 2004, he was referred to the emergency room with a diagnosis of septic shock, dehydration, and liver failure. (Id., Ex. A at 4.) He was later transferred to Stanford University Hospital for a liver transplant, which took place on June 15, 2004. (Id., Ex. A at 4-6.) A.G. developed other complications, and he eventually had to have necrotic tissue on his fingers and toes amputated. (Id., Ex. A at 7.)

B. The Food and Drug Administration's Role in Regulating Drugs

Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, a drug manufacturer must obtain Food and Drug Administration ("FDA") approval before a new drug may be marketed and sold to the public. See 21 U.S.C. § 355. The process for approval requires

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[1] (Plaintiffs' Response to Perrigo's Motion for Summary Judgment, Ex. A at 3, hereafter, "Opposition," Docket Item No. 165.) Plaintiffs have moved for leave to file a supplemental reply. (Docket Item No. 221.) However, since the proffered supplemental reply is entirely duplicative of previous briefing, this motion is DENIED.

submission of a new drug application ("NDA") to demonstrate that the drug is "safe and effective." 21 U.S.C. § 355(a)-(i). The proof of the efficacy and safety of the drug must be based on extensive laboratory testing. 21 U.S.C. § 355(b). Drug manufacturers also must submit to the FDA "specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1). The label must contain a "warnings" section which describes "clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug)." 21 C.F.R. § 201.57(c)(6)(I). When the drug is approved, the FDA includes it in its published list of approved drugs. See 21 U.S.C. § 355(j)(7). The drug is then referred to as a "listed drug." Id. § 355(j)(2)(A)(i). A listed drug may also be referred to as an "innovator" or "pioneer" drug. See, e.g., Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1494, 1497-98 (D.C. Cir. 1996).

Before 1984, generic drug manufacturers were required to submit their own NDA. See Tri-Bio Labs., Inc. v. United States, 836 F.2d 135, 138-39 (3d Cir. 1987). With the Drug Price Competition and Patent Term Restoration Act of 1984, Congress relaxed the procedure for obtaining approval from the FDA to market and sell a generic drug, allowing the generic maker to submit an abbreviated NDA ("ANDA"). Id.; see 21 U.S.C. § 355(j), 35 U.S.C. §§ 156, 271, 281. The ANDA must certify that the generic manufacturer will produce a bio-equivalent of the listed drug and that the labeling and warnings of the generic drug are the same as those of the listed drug. 21 U.S.C. § 355(j)(2)(A).

C. Procedural History

On October 12, 2005, Plaintiff Margarita Gaeta filed a Complaint, as guardian ad litem for her son, A.G., against Perrigo and Longs Drug Stores Corporation. (Complaint, Docket Item No. 1.) The Complaint has been amended twice, adding Augustine Gaeta as a Plaintiff and PAR and BASF as Defendants. (See Docket Item Nos. 6, 29.) On February 28, 2006, Plaintiffs filed a Second Amended Complaint, which remains the operative complaint. In the Second Amended Complaint,

Plaintiffs allege that Defendants are liable for injuries A.G. sustained as a result of ingesting ibuprofen manufactured and distributed by Defendants. (Id.)

Plaintiffs allege the following causes of action against Defendants: (1) Defective Design; (2) Marketing Defect; (3) Breach of Express Warranty; (4) Breach of Implied Warranty; (5) Negligence and Gross Negligence; and (6) Deceit by Concealment pursuant to Cal. Civ. Code §§ 1709-1710. (SAC ¶¶ 33-53.)

Presently before the Court is Perrigo's motion for summary judgment.

III. STANDARDS

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The purpose of summary judgment "is to isolate and dispose of factually unsupported claims or defenses." Celotex v. Catrett, 477 U.S. 317, 323-24 (1986).

The moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying the evidence which it believes demonstrates the absence of a genuine issue of material fact." Id. at 323. The non-moving party must then identify specific facts "that might affect the outcome of the suit under the governing law," thus establishing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e).

When evaluating a motion for summary judgment, the court views the evidence through the prism of the evidentiary standard of proof that would pertain at trial. Anderson v. Liberty Lobby Inc., 477 U.S. 242, 255 (1986). The court draws all reasonable inferences in favor of the non-moving party, including questions of credibility and of the weight that particular evidence is accorded. See, e.g., Masson v. New Yorker Magazine, Inc., 501 U.S. 496, 520 (1992). The court determines whether the non-moving party's "specific facts," coupled with disputed background or contextual facts, are such that a reasonable jury might return a verdict for the non-moving party. T.W. Elec. Serv. v. Pac. Elec. Contractors, 809 F.2d 626, 631 (9th Cir. 1987). In such a case,

summary judgment is inappropriate. Anderson, 477 U.S. at 248. However, where a rational trier of fact could not find for the non-moving party based on the record as a whole, there is no "genuine issue for trial." Matsushita Elec. Indus. Co. v. Zenith Radio, 475 U.S. 574, 587 (1986).

IV. DISCUSSION

Perrigo moves for summary judgment on the ground that all of Plaintiffs' claims are preempted by the FDCA. (Motion at 7.)

The Supremacy Clause of United States Constitution provides that federal laws and treaties "shall be the supreme law of the land." U.S. Const. Art. VI, Cl. 2. The United States Supreme Court has recognized three types of federal preemption of state law under the Supremacy Clause: (1) express preemption, where Congress states explicitly the preemptive effect of its legislation on state law; (2) field preemption, where Congress intends for federal law to occupy exclusively an entire field of regulation; and (3) conflicts preemption, where it is impossible for a private party to comply with both state and federal requirements. English v. General Electric Co., 496 U.S. 72, 78-79 (1990).

The Food and Drug Modernization Act of 1997 ("Modernization Act") amended the FDCA to provide for express preemption of state laws regarding non-prescription, "OTC" drugs. 21 U.S.C. § 379r(a). However, § 379 has a savings clause, which provides that preemption provision does not affect "the liability of any person under the product liability law of any State." § 379r(e). The scope of the term "product liability law" as used in the statute is not exactly clear. The California Court of Appeal has found that the § 379r savings clause does not cover all "common law and statutory actions imposing liability on commercial sellers of products." Kanter v. Warner-Lambert Co., 99 Cal. App. 4th 780, 790-91 (2002). Regardless, the savings clause "does not bar the ordinary working of conflict pre-emption principles." Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 869 (2000). Under such principles, a court should "decline to give broad effect to savings clauses where doing so would upset the careful regulatory scheme established by federal law." United

States v. Locke, 529 U.S. 89, 106-07 (2000). Thus, the Court proceeds to consider whether conflicts between common law and federal law upset the regulatory scheme of the FDA.

Consideration of conflicts preemption under the Supremacy Clause "starts with the basic assumption that Congress did not intend to displace state law." Building and Const. Trades Council of Metro. Dist. v. Assoc. Builders and Contractors of Mass./RI, Inc., 507 U.S. 218, 224 (1993). In order for a court to find conflicts preemptions, there must be "clear evidence of a conflict." Geier, 529 U.S. at 885. Conflicts preemption can occur with respect to the regulations of a federal agency because regulations promulgated pursuant to federal statutory authority "have no less pre-emptive effect than federal statutes." Fidelity Federal Savings and Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982). The preemption of such regulations may be challenged only to determine whether they exceed statutory authority or were made arbitrarily. Id.

In approving an ANDA for a generic drug, the FDA requires the drug's manufacturer "to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the [ANDA]." 21 C.F.R. § 314.127; 21 U.S.C. § 355(j)(2)(A)(v). "Labeling" is defined by statute as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C § 321(m). Thus, labeling "embraces advertising or descriptive matter that goes with the package in which the articles are transported," in addition to any label that may be placed directly on a pill bottle. Kordel v. United States, 335 U.S. 345, 350 (1948). The FDA will allow certain changes to the label in an approved petition under § 314.93, which provides:

> A person who wants to submit an abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application.

21 C.F.R. § 314.93.

The FDA may withdraw approval for an ANDA if the agency finds that "the labeling for the drug product . . . is no longer consistent with that for the listed drug" or that the label "is false or

misleading in any particular." 21 C.F.R. § 314.150(b)(3), (b)(10). For a non-generic drug, a Changes Being Effected ("CBE") supplement to a label "is appropriate to amend the labeling for an approved product . . . to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug." 73 Fed. Reg. 2848, 2849 n.1 (background to proposed rule). However, "CBE changes are not available for generic drugs approved under an [ANDA] . . . . To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug." Id.; see 21 CFR 314.150(b)(10); 57 Fed. Reg. 17950, 17953, and 17961. Under these regulations, a generic drug manufacturer cannot change its label to add a warning or contraindication without FDA approval.[2]

In 2006, the FDA amended its regulations and set forth its position that "under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law." 71 Fed. Reg. 3922, 3934. The FDA's reasons for this position are as follows:

> State law actions can rely on and propagate interpretations of the act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate. For example, courts have rejected preemption in State law failure-to-warn cases on the ground that a manufacturer has latitude under FDA regulations to revise labeling by adding or strengthening warning statements without first obtaining permission from FDA. In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act.
> . . .
>
> According to many courts, State law serves as an appropriate source of supplementary safety regulation for drugs by encouraging or requiring manufacturers to disseminate risk information beyond that required by FDA under the act. In fact, FDA interprets the act to establish both a "floor" and a "ceiling," such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.
> . . .

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[2] Id. The manufacturer of the generic drug may only unilaterally change its label to reflect "differences in expiration date . . . or omission of an indication or other aspect of labeling protected by patent." 21 C.F.R. § 314.127(a)(8).

> FDA has previously found that labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to "lose its significance." Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health. Similarly, State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act.

Id. at 3934-35 (citations ommitted).

In the absence of clear authority to the contrary, a court is to give deference to an agency's interpretation of the scope of its authority to regulate. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843-44 (1984); see Medtronic, Inc. v. Lohr, 518 U.S. 470, 505-06 (1996) (Breyer, J., concurring) (considering preemptive effect of FDA regulations, in light of the FDA's position that certain claims were not preempted). Under this principle, "state tort law which would hold a generic drug manufacturer liable for failing to modify a label . . . conflict[s] with the FDCA," and any such claims are preempted by FDA regulations to the extent they seek to do so. Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 537-38 (E.D. Pa. 2006) aff'd, Colacicco v. Apotex Inc., 2008 WL 927848 (3d Cir. 2008); cf. Papike v. Tambrands Inc., 107 F.3d 737, 742 (9th Cir. 1997).

In this case, Plaintiffs allege causes of action for: (1) Defective Design; (2) Marketing Defect; (3) Breach of Express Warranty; (4) Breach of Implied Warranty; (5) Negligence and Gross Negligence; and (6) Deceit by Concealment. (SAC ¶¶ 33-53.) With respect to each of these causes of action, Plaintiffs allege, at least in part, that Defendants failed to warn individuals with appropriate materials. (Id.) Specifically, in pleading their Defective Design cause of action, Plaintiffs allege that Perrigo "failed to adequately and completely inform or warn of the risks of liver injury and renal failure associated with the use of OTC ibuprofen to treat children for pain or fever." (Id. ¶ 35.) In their Marketing Defect cause of action, Plaintiffs allege that "[t]he warnings and instructions that accompanied the defendants' drugs provided inadequate warning to the consumer and/or healthcare provider about the risk of acute liver failure." (Id. ¶ 40.) Similar allegations are made in Plaintiffs' Breach of Warranty, Negligence, and Deceit causes of action. (Id. ¶¶ 42-53.)

Perrigo's OTC ibuprofen was approved by the FDA under the ANDA process in 1987, which indicates that the FDA found it safe and effective. (Declaration of Robert Pinco in Support of Motion for Summary Judgment ¶ 7, hereafter, "Pinco Decl.," Docket Item No. 159.) In 2002, the FDA engaged in a comprehensive review regarding the safety of ibuprofen. (Id. ¶ 8.) The FDA concluded that warning for risk of liver injury was not scientifically supported by the available data. 67 Fed. Reg. 54139, 54145-56. The FDA also considered warning for risk of kidney injury and found that "the consumer labeling for OTC ibuprofen should have a warning directed [to] those at risk for the development of acute renal failure associated with the use of the product." Id. at 54144-45. However, the FDA has not yet approved inclusion of the warning. 71 Fed. Reg. 77314, 77316.

At the time it was administered to A.G., Perrigo's ibuprofen followed the labeling for the listed drug, which contained the warnings mandated by the FDA. (Pinco Decl. ¶¶ 7, 8.) Thus, the Court finds that Perrigo has complied with the labeling requirements that the FDA has set for OTC ibuprofen. Plaintiffs' causes of action seek to hold Perrigo liable for, in part, failing to warn of risks on the labeling for its drug. Since including these warning would put the Perrigo's ANDA in jeopardy for failing to conform with the FDA's approved labeling for the listed drug, Plaintiffs' state law causes of action conflict with Perrigo's obligations under federal law.

Accordingly, the Court GRANTS in part Perrigo's Motion for Summary Judgment. The Court finds that Plaintiffs' causes of action are preempted to the extent that they allow for liability based on a lack of adequate warning on the company's OTC generic drug labeling for its 200mg ibuprofen product.

V. CONCLUSION

The Court GRANTS Perrigo's Motion for Summary Judgment. Perrigo's Motion to Strike the Testimony of Randall Tackett,[3] an expert designated to testify about warning labels, is DENIED as moot.

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[3] (Docket Item No. 188.) Plaintiffs have also moved for an extension of time to respond to Perrigo's motion to strike. (Docket Item No. 225.)

The Court defers entering judgment in favor of Perrigo. The Court sets a Further Case Management Conference for **June 30, 2008 at 10 a.m.** The parties shall meet and confer and file a Joint Case Management Statement on or before **June 20, 2008.** The Statement shall address what claims, if any, remain at issue in this case. Specifically, whether any of Plaintiffs' claims are based on another non-preempted theory of recovery, such as, design defect for failure to conform to the specification of the FDA approved form of the drug.

This Order terminates Docket Item Nos. 156, 188, 221, and 225.

Dated: June 13, 2008

JAMES WARE
United States District Judge

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Dated: June 13, 2008

Richard W. Wieking, Clerk

By: /s/ JW Chambers
Elizabeth Garcia
Courtroom Deputy

United States District Court
For the Northern District of California